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| 10/019,400 | 12/28/2001 | Shinji Yamasoto | 7388/72545 | 1864 |

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EXAMINER

PICKETT, JOHN G

ART UNIT PAPER NUMBER

3728

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,400

Applicant(s)

YAMASOTO ET AL.

Examiner

Gregory Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office action acknowledges the applicant's Amendment submitted 2 September 2004. Claims 1-5 and 13-17 are pending in the application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuichi (JP 04-189779 A) in view of Caggiano (US 4,861,632) and Wilking (US 5,698,217).

Regarding claims 1 and 2, base reference Yuichi discloses a patch package (Figures 1 and 2) with a first sheet (11) having a first moisture-permeable layer (14) of unspecified moisture permeability rate, a first screen material layer (12) for blocking penetration of moisture and light, and a first hygroscopic material layer (13) comprising a first resin containing an unspecified wt% of inorganic filler (see USPTO translation 2003-3872, page 5, lines 13-16). Yuichi discloses forming a bag by using a single sheet folded such that the moisture-permeable layer (14) is oriented on the inner portion of the bag and heat-sealing the edges (see USPTO translation 2003-3872, page 6, lines 15-19). Yuichi is capable of receiving a pharmaceutical patch.

Yuichi lacks or does not expressly disclose the use of two sheets to form the bag, a screen material of two layers, a moisture permeability rate of 40-120 g/m²/day, and a 20-40 wt% of organic filler.

As to the wt% of organic filler, Yuichi discloses the general conditions claimed by the applicant. Yuichi suggests modification of material to effect performance of the water-absorbing layer (see USPTO translation 2003-3872, page 6, lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the organic filler in the ranges claimed by the applicant in order to ensure adequate moisture absorbency. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. One of ordinary skill in the art would have reasonably expected success since the materials all perform as expected.

As to the moisture-permeability rate, Yuichi discloses the general conditions claimed by the applicant. Yuichi suggests modification of thickness and material to adjust the water absorbing speed (see USPTO translation 2003-3872, page 6, lines 8-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the moisture permeability layer of Yuichi in the ranges claimed by the applicant in order to ensure adequate absorbency. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ

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233. One of ordinary skill in the art would have reasonably expected success since the materials all perform as expected.

As to the use of two sheets to form the bag, Caggiano discloses that a moisture-absorbing bag (Figure 4) formed from two sheets and sealed at their edges was an equivalent structure known in the art at the time the invention was made. Therefore, because these two bag forming methods were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the two sheet method of Caggiano for the single sheet method of Yuichi. One of ordinary skill in the art would have reasonably expected success since the bag would perform equally well with either forming method.

As to the screen material of two layers, Wilking discloses that it was known in the art at the time the invention was made to use low density polyethylene (LDPE) or high density polyethylene (HDPE) with a foil laminate in a patch package having moisture absorbing properties (see for example, Wilking Col. 4, lines 47-54). Yuichi discloses a first resin as belonging to the olefin group (in which polyethylene is included). Yuichi suggests modification of the material to effect performance (see for example, USPTO translation 2003-3872, page 6, lines 8-10). Yuichi-Caggiano as applied above, discloses the claimed invention except for the first and second resin of LDPE and the screen layer being an HDPE-foil laminate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the package of Yuichi-Caggiano with a first and second resin of LDPE and the screen layer of an HDPE-foil laminate, since it has been held to be within the general skill of a worker in

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the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 3, the patch package of Yuichi-Caggiano-Wilking, as applied to claim 2 above, discloses the general conditions claimed by the applicant. The base reference Yuichi is on the same scale claimed by the applicant (see USPTO translation 2003-3872, page 5, lines 7-11). Yuichi suggests modification of the thickness to effect performance (see for example, USPTO translation 2003-3872, page 4, lines 10-12, page 6, lines 8-10). As to the specific thickness ranges, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 4, Yuichi discloses forming a bag by heat-sealing the edges (see USPTO translation 2003-3872, page 6, lines 15-19). Yuichi-Caggiano-Wilking as applied to claim 1 above, discloses the claimed invention except for the specific heat seal strengths. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Yuichi-Caggiano-Wilking with the claimed heat seal strengths, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

4. Claims 5, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilking (US 5,698,217) in view of Yuichi (JP 04-189779 A) and Tsukahara et al (H-7-28550).

Regarding claim 5, the base reference Wilking discloses a packaged patch (10) comprising a patch (32, 34, 36) having a support (32) and a pressure sensitive adhesive (34) laminated on the support (see Col. 5, lines 29-35) within a patch package (12) comprising a first screen material layer (14) of two layers (i.e. foil and HDPE, see Col. 4, lines 51-54) and a second screen material layer (16) of two layers (i.e. foil and HDPE, see Col. 4, lines 51-54). Wilking also discloses a package in the claimed surface area ratio (see Wilking Figure 1 as compared to Figure 1 of the instant application), heat-sealing the screen material to form a package, and a separate package (20) of hygroscopic material (with an inorganic filler, see Col. 4, lines 1-14) separated by a moisture permeable layer of resin for the removal of moisture from the inside of the package (see for example, Col. 3, lines 30-33).

Wilking lacks, or does not expressly disclose, a first and second moisture permeable layer of the claimed moisture permeability rate and a first and second hygroscopic material layer of the claimed wt% of inorganic filler, laminated to the screen material layers, nor a pressure sensitive adhesive that is composed mainly of styrene-isoprene-styrene blocked copolymer.

One of ordinary skill in the art would have recognized that the package of contains a plurality of components. Yuichi discloses a desiccant made integral with the walls of the package, and having the hygroscopic material and moisture-permeable material arranged as claimed by the applicant. It would have been obvious to one of ordinary skill in the art at the time the invention was made, to integrate the hygroscopic material of Wilking into the walls of the package as taught by Yuichi in order to reduce

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the number of parts of the package. It has been held that forming in one piece an article that has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Concerning the moisture-permeability rate, Wilking-Yuichi discloses the general conditions claimed by the applicant. Yuichi suggests modification of thickness and material to adjust the water absorbing speed (see USPTO translation 2003-3872, page 6, lines 8-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the moisture permeability layer of Wilking-Yuichi in the ranges claimed by the applicant in order to ensure adequate absorbency. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. One of ordinary skill in the art would have reasonably expected success since the materials all perform as expected.

Concerning the wt% of organic filler, Wilking-Yuichi discloses the general conditions claimed by the applicant. Yuichi suggests modification of material to effect performance of the water-absorbing layer (see USPTO translation 2003-3872, page 6, lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the organic filler in the ranges claimed by the applicant in order to ensure adequate moisture absorbency. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ

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233. One of ordinary skill in the art would have reasonably expected success since the materials all perform as expected.

Concerning the pressure sensitive adhesive that is composed mainly of styrene-isoprene-styrene blocked copolymer, Tsukahara et al shows that pressure sensitive adhesive that is composed mainly of styrene-isoprene-styrene blocked copolymer was an equivalent structure to the pressure sensitive adhesive of Wilking, which was known in the art at the time the invention was made. Therefore, because these two pressure sensitive adhesives were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it an obvious matter of design choice to substitute the adhesive of Tsukahara et al for the adhesive of Wilking depending upon their suitability to the intended use.

Regarding claims 13, 14 and 15, the package of Wilking-Yuichi-Tsukahara, as applied to claim 5 above, discloses the claimed invention.

As to claim 16, Wilking discloses estradiol (Col. 3, lines 18-21).

As to claim 17, Wilking discloses smoking cessation aides (Col. 3, lines 18-21).

Response to Arguments

5. Applicant's arguments regarding claims 1-4, filed 2 September 2004, have been fully considered but they are not persuasive.

6. In response to applicant's arguments, the recitation "adapted for receiving a pharmaceutical patch" has not been given patentable weight because the recitation

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occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The claimed structures of the instant application are able to stand alone. Further, the package of Yuichi is capable of receiving a pharmaceutical patch.

7. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that Caggiano does not disclose the claimed materials or that Wilking requires a separate desiccant pack, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

8. In response to the applicant's assertion that the passage cited by the examiner in Wilking requires paper for the screen material layer, the examiner respectfully points to

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the passage cited by the applicant at column 4, line 51, "paper or foil" (emphasis added). Applicant underlines "paper" in the presented arguments but it is clear from this passage that in the heat-sealable embodiment, it is paper or foil, but not both.

9. Applicant's arguments, see page 13, filed 2 September 2004, with respect to the rejection(s) of claim(s) 5 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the Wilking and Yuichi references. The interpretation has been presented in the rejections above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 571-272-4560. The examiner can normally be reached on Mon-Fri, 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Greg Pickett
Examiner
17 November 2004



Mickey Yu
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